

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: April 11, 2017

SUBJECT: Imidacloprid: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment

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Summary and Conclusions

Imidacloprid was last reviewed in the Health Effects Division's Toxicology and Epidemiology Branch on 8/27/08 (M. Hawkins and J. Cordova, DP Barcode D353983). At the time, a large number of single chemical incidents (n=436) involving imidacloprid only were reported to OPP's Incident Data System (IDS) from January 1, 2000 to August 27, 2008. Based on the frequency of incidents identified; further analysis of imidacloprid incidents was recommended for the draft risk assessment phase of registration review. This memo provides an updated Tier I review of imidacloprid incidents.

In the current IDS analysis from January 1, 2011 to April 26, 2016, there were 44 incidents reported for the single chemical (only) in the database involving imidacloprid in Main IDS and additional 518 incidents reported involving multiple active ingredients. For Aggregate IDS, there were 2,828 incidents reported in the database involving imidacloprid. A query of SENSOR-Pesticides from 1998-2013 identifies a total of 318 cases involving imidacloprid (PC Code 129099). Of these, 114 cases involved a single active ingredient (ai). A query of National Pesticide Information Center (NPIC) from January 1, 2010 to December 31, 2015, identified a total of 111 human incidents involving imidacloprid reported to NPIC. Ninety-six cases were reported to California's Pesticide Incident Surveillance Program (PISP) between 2010 and 2013 that involve the active ingredient, imidacloprid, in combination with other pesticides. Only three of these cases involved the single ingredient imidacloprid.

The AHS is a high quality, prospective epidemiology study evaluating the link between pesticide use and various health outcomes including cancer. Imidacloprid is not included in the AHS, and therefore this study does not provide information for this report.

Detailed Review

I. ACTION REQUESTED

Imidacloprid is being considered under the FQPA-mandated Registration Review program established to review, on a 15 year cycle, pesticides for which a Re-registration Eligibility Decision has been made. One component of the Agency's Registration Review Program is consideration of human incident data. In conjunction with a human health risk assessment based on other data sources, human incident data can assist the Agency in better defining and characterizing the risk of pesticides/pesticide products.

Reports of adverse health effects allegedly due to a specific pesticide exposure (*i.e.*, an "incident") are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated or otherwise confirmed. Typically, causation cannot be determined based on incident data. However, incident information can be an important source of feedback to the Agency: incidents of severe outcome, or a suggested pattern or trend among less severe incidents, can signal the Agency to further investigate a particular chemical or product. Epidemiology studies can also be useful and relate the risk of disease, *e.g.*, cancer, and exposure to an agent such as a pesticide product in the general population or specific sub-groups like pesticide applicators.

II. BACKGROUND

Imidacloprid is a systemic insecticide registered to control soil insects, sucking insects, chewing insects, and termites. It is effective against the larval, nymphal and adult stages. The primary mode of action is the disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors. Imidacloprid is registered for use on several agricultural products, ornamental turf/plant products, seed treatments, pet care products, as well as structural pest products.

For imidacloprid, this updated Tier I analysis reviews a broad set of available incident data. This updated Tier I imidacloprid analysis includes human observation data from the following sources:

- OPP's Incident Data System (IDS) database;
- National Institute for Occupational Health's Sentinel Event Notification System for Occupational Risk-Pesticides (NIOSH SENSOR-Pesticides);
- the Agency-sponsored National Pesticide Information Center (NPIC); and
- California's Pesticide Incident Surveillance Program (PISP).

Also included in this review are trend analyses and summaries (root cause analysis) with respect to incidents was performed, as well as additional analysis on a product-specific (as opposed to active ingredient) basis.

III. RESULTS/DISCUSSION

As indicated above, incident information can provide important feedback to the Agency, assisting in determining actual real-world exposures and risks posed by pesticides/pesticide products. Incident data are collected systematically, but differently, across the different databases used by the Agency with respect to such issues as coverage, certainty/confidence, fields/parameters reported, and usability. The aforementioned four pesticide incident data sources (IDS, NPIC, California PISP, and NIOSH SENSOR-Pesticides) were used in this imidacloprid report since they provide useful content and historical perspective. Various other comparable sources of data are available (e.g. the Bureau of Labor Statistics, emergency room outpatient surveillance, National Poison Data System (NPDS), etc.) but are not included in this review. By looking across the four data sources which were used, the Agency is confident that we are considering adequate and appropriate information to discern trends and patterns in imidacloprid associated acute pesticide poisonings, or "incidents."

a. OPP Incident Data System (IDS) (2011-2016)

The OPP IDS includes reports of alleged human health incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6 (a) (2) reports from registrants and reports from other federal and state health and environmental agencies and individual consumers. Since 1992, OPP has compiled these reports in IDS. IDS contain reports from across the U.S. and most incidents contained in the system have all relevant product information recorded. Case reports or "narratives" are provided for each incident, with varying levels of detail; however, there is no effort at validating or assessing how likely it is that the reported exposure is causally related to the reported outcome. Because IDS has such extensive coverage, it is useful for providing temporal trend and geographic pattern information. The system is also useful for determining whether risk mitigation has helped reduce potential pesticide exposure through a decreased number of reported incidents.

For this evaluation, the OPP IDS was utilized for pesticide incident data on the active ingredient imidacloprid (PC Code: 129099). IDS records incidents in one of two modules: Main IDS and Aggregate IDS. Main IDS contains incidents resulting in higher severity outcomes and provides more detail with regard to case specifics. This system stores incident data for death, major and moderate incidents (as well as some less severe incidents provided generally by patient portals or individuals), and it includes information about the location, date and nature of the incident, often in narrative form. Main IDS incidents involving only one active ingredient (as opposed to pesticide products with multiple active ingredients) are considered to provide more certain information about the potential effects of exposure from the pesticide. The higher severity outcomes include:

- H-A (death): If the person died;
- H-B (major): If the person alleged or exhibited symptoms which may have been life-threatening, or resulted in adverse reproductive effects or in residual disability; and
- H-C (moderate): If the person alleged or exhibited symptoms more pronounced, more prolonged or of a more systemic nature than minor symptoms, usually some form of treatment of the person would have been indicated, symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.

Aggregate IDS contains incidents resulting in less severe human incidents (minor, unknown, or no effects outcomes). These are reported by registrants only as counts in what are aggregate summaries. The less severe human incidents include:

- H-D (minor): If the person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved rapidly and usually involve skin, eye or respiratory irritation; and
- H-E/H (unknown or no effects): If symptoms are unknown, unspecified or are alleged to be of a delayed or chronic nature that may appear in the future.

For the Main IDS, from January 1, 2011 to April 26, 2016, there are 560 cases reported that involve the active ingredient (ai) imidacloprid. Of these 560 cases, 44 incidents involved the single active ingredient imidacloprid only and the other 516 incidents involved multiple active ingredients. Of the 560 reported imidacloprid incidents, there were 2 deaths, 35 of these incidents were classified as major severity, 521 incident were classified as moderate severity, one incident was classified as minor severity, and one incident was classified as having no or unknown effects.¹ The two deaths took place in 2015. One death was due to a suicide. The other reported death involved a resident who passed away at a residence that was treated with three different products (Reg. Nos. 432-1483, 432-772, and 432-1483). At the time of this memo, this case is under investigation while they wait for the coroner report. This incident is further described in Appendix A.

¹ Minor severity incidents and incidents with no or unknown effects are typically reported to the Aggregate IDS, but do occasionally get reported to the Main IDS. For imidacloprid, there are 2827 more minor severity incidents and one additional incident with no or unknown effects reported to Aggregate IDS from 2011 to April 26, 2016.

For this analysis, the imidacloprid incidents reported to Main IDS from January 1, 2015 to April 26, 2016 were reviewed further for exposure scenario and reported symptoms (n=156).² The 156 incidents that were reviewed all took place in a residential setting. These incidents are described in Appendix A. Individuals were most exposed due to exposure to a pet-applied product (n=135). Individuals reported being exposed during application of the product to the pet or being exposed due to contact with their treated pet following application of the product. Exposure scenarios are described in Table 1.

Table 1. Exposure Scenario Frequency of Imidacloprid Incidents Reported to Main IDS (2015-2016)	
Exposure Scenario	Number of Reported Incidents
Exposure to Pet Product	135
Residential Applicator	9
Residential Post Application Exposure	8
Contact with Product (accidentally sprayed by applicator, product clean up)	3
Residential Drift	1
Total	156

Based on the IDS reports, symptoms most often reported were dermal (n=80), neurological (n=68), gastrointestinal (n=27), respiratory (n=23), ocular (n=13), and cardiovascular (n=5). Note that a patient could exhibit multiple symptoms. Dermal symptoms reported include rash, itchiness, blisters, dermatitis, pruritus, dermal irritation, erythema, eczema, urticaria, blepharitis, flushed sensation, redness, and swelling. Neurological symptoms reported include altered taste, tremors, hallucinations, paresthesia, ataxia, seizure, confusion, sweating, headaches, migraines, dizziness, numbness, and muscle weakness. Gastrointestinal symptoms reported were diarrhea, constipation, dysphagia, anorexia, abdominal pain, nausea, and vomiting. Respiratory symptoms reported included dyspnea, difficulty breathing, asthma attack, difficulty swallowing, throat tightness, wheezing, sore throat, nasal irritation, coughing, choking, nasal discharge, congestion, bronchitis, laryngeal irritation, respiratory depression, and respiratory irritation. Ocular symptoms reported were redness, dryness, itchiness, conjunctivitis, mydriasis, ocular irritation, ocular swelling, and lacrimation. Cardiovascular symptoms reported include tachycardia, heart palpitations, and chest discomfort.

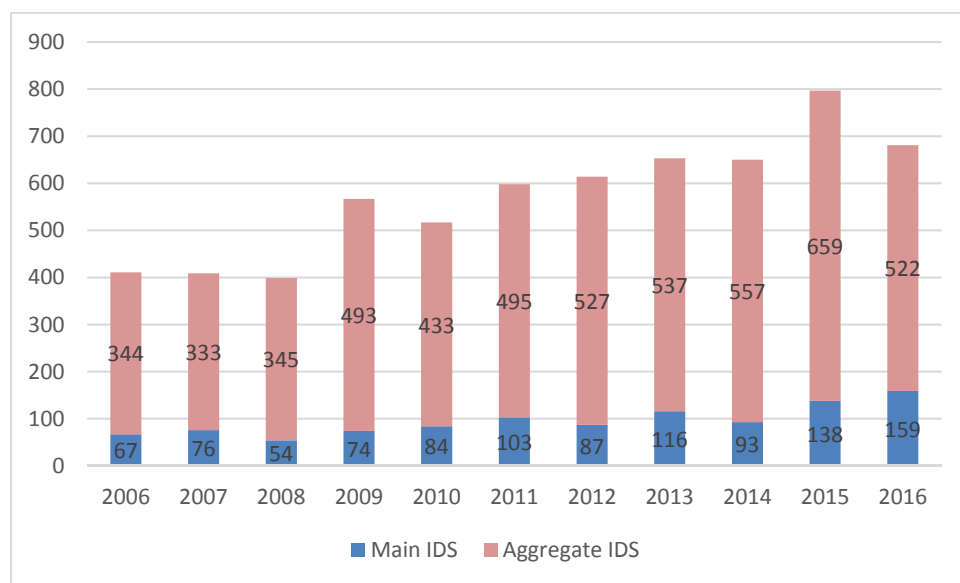
In Aggregate IDS, queried from January 1, 2011 to April 26, 2016, there were 2,828 human incidents involving imidacloprid. One of these incidents was classified as having no or unknown effects and 2,827 incidents were classified as minor severity. Minor severity means that a person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved

² There was one suicide, 19 duplicate incident reports, and two incidents with no available information that were not considered further in this analysis.

rapidly and usually involved skin, eye, or respiratory irritation. Because these incidents fall within the categories reported as counts (which includes minor, unknown or no effects), there is no unique report that provides details about the incident and single chemical incidents are not distinguished from multiple chemical incidents; however, in general a high frequency of incidents may indicate that there is a high potential for exposure or elevated acute toxicity and vice versa.

The imidacloprid incidents reported to IDS from 2006 to 2016, appear to be increasing from 2006 to 2015, then decreasing in 2016 (Figure 1).

Figure 1. Number of Imidacloprid Incidents Reported to IDS from 2006 to 2016



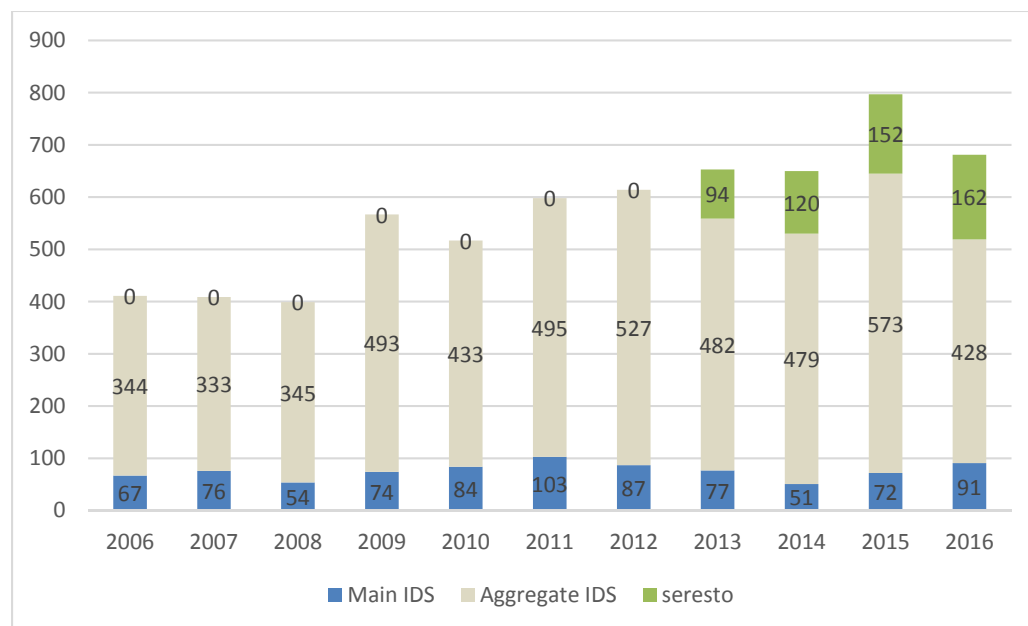
The top five most implicated imidacloprid products in IDS are listed in Table 2. Three of the products are pet applied products and two products are for residential use on lawns and ornamentals. The most implicated imidacloprid product (Seresto Collar, Reg. No. 11556-155) is a flea and tick collar used on dogs and cats. It contains 10% imidacloprid and 4.5% flumethrin. The second most implicated product is an insecticide (Reg. No. 72155-29) applied to lawns and building foundations to treat a variety of pests including ants, crickets, fleas, flies, mosquitoes, spiders, and ticks. It can be applied with pump style tank sprayer or hose-end sprayer. The third most implicated product is an insecticide/miticide/fungicide (Reg. No. 72155-73) that can be applied to roses, flowers, ground cover, vines, ornamentals, shrubs and trees to treat insects, mites and diseases. It can be applied with pump style tank sprayer or hose-end sprayer. The fourth and fifth most implicated products are K9 Advantix II Extra Large Dog (Reg. No. 11556-144) and Advantage II Large Cat (Reg. No. 11556-155) are both spot-on products applied to pets to control fleas and ticks.

Table 2. Top 5 Implicated Imidacloprid Products in IDS from 2011 to 2016					
Product Reg. No.	Product Name	Alternate Name*	Incident Count in Main IDS	Incident Count in Aggregate IDS	% Imidacloprid Incidents
11556-155	PNR1427 Insecticide	SERESTO	155	239	12%
72155-29	IMIDACLOPRID 0.72%+BETA-CYFLUTHRIN 0.36% CONCENTRATE	BAYER ADVANCED COMPLETE INSECT KILLER	31	294	10%
72155-73	IMIDACLOPRID + TAU-FLUVALINATE + TEBUCONAZOLE CONCENTRATE INSECTICIDE, MITICIDE, AND FUNGICIDE	3-IN-1 DISEASE & MITE CONTROL CONCENTRATE	15	277	9%
11556-144	K9 ADVANTIX II EXTRA LARGE DOG	Not Applicable	39	245	8%
11556-152	ADVANTAGE II LARGE CAT	Not Applicable	32	198	7%

*The "Alternate Name" column includes one of the alternate names that this product is sold as, but there may be others.

Seresto Collar (Reg. No. 11556-155) was registered on March 16, 2012. The number of Seresto Collar incidents reported to IDS has increased every year from 2013 to 2016 (Figure 2).

Figure 2. Number of All Imidacloprid and Seresto Incidents Reported to IDS from 2006 to 2016



b. SENSOR-Pesticides

The Center for Disease Control's National Institute for Occupational Health (CDC/NIOSH) manages a pesticide surveillance program and database entitled the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides.³ This database includes pesticide illness case reports in 12 states from 1998-2013. Participating states are: California, Florida, Iowa, Louisiana, Michigan, Nebraska, New Mexico, New York, North Carolina, Oregon, Texas and Washington. The participating states for a given year vary depending on state and federal funding for pesticide surveillance.

Cases of pesticide-related illnesses in the SENSOR-Pesticides database are ascertained from a variety of sources, including: reports from local Poison Control Centers, state Department of Labor workers' compensation claims when reported by physicians, reports from state Departments of Agriculture, and physician reports to state Departments of Health. Although both occupational and non-occupational incidents are included in the database, the SENSOR coordinators primarily focus their follow-up case investigation efforts on the occupational pesticide incidents. The SENSOR coordinator at the state Department of Health will follow-up with cases and work to obtain medical records in order to verify exposure scenario, symptoms, severity, and health outcome. Using standardized protocol and case definitions, SENSOR coordinators at state Departments of Health enter the incident interview description provided by the case, medical report, physician and patient into the SENSOR data system.

All SENSOR-Pesticide cases must report a minimum of two health effects in order to be included in the aggregate database that EPA uses for incident analyses. Evidence for each case is evaluated for its causal relationship between exposure and illness based on the NIOSH case classification index. Ninety-eight percent of SENSOR-Pesticides cases are classified as definite, probable, or possible, and 2% of the cases are classified as suspicious. Unlikely, asymptomatic, and unrelated cases, as well as those with insufficient information, are not included in the SENSOR-Pesticides database.

A query of SENSOR-Pesticides from 1998-2013 identifies a total of 318 cases involving imidacloprid (PC Code 129099). Of these, 114 cases involved a single active ingredient (ai). Two cases were high in severity, 18 cases were moderate in severity and 94 cases were low in severity. Forty-eight percent of all cases were applying or handling the product at the time of exposure. Sixty-one percent of cases were residential and 39% of cases were occupational.

Of the 70 residential cases reported to SENSOR-Pesticides the majority involved homeowner applications to a pet, followed by applications to lawns. Overall, the most common reason for a residential exposure and illness from imidacloprid was due to applications of topical solution spot-on products onto pets (n=29). A total of 32 residential cases were applying products to their pet or were nearby an application to a pet when exposed. While 29 of these were Advantage topical solution products, three of these cases did not report a specific product. Further, 19 of the 32 pet product exposure cases involved individuals that got the product in their eyes during application or afterwards from contact with the treated animal. The second most common

³ SENSOR-Pesticides webpage: <http://www.cdc.gov/niosh/topics/pesticides/overview.html>

residential exposure to imidacloprid (n=12) resulted from applications made to lawns. With regard to the case's specific activity when exposed: 29 cases were applying an imidacloprid product at the time they were exposed and made ill; 20 cases were conducting routine indoor living activities when exposed; 10 cases were conducting routine outdoor living activities when exposed; the remaining 11 were either other or unknown activity at the time of exposure.

Of the 44 work-related cases; 27 were applying or handling the product at the time they were exposed and made ill. Fifteen occupational cases were conducting non-handling work activity when they were exposed and made ill; nine of these non-handling exposure cases occurred on agricultural establishments and the remaining six of these cases were non-agricultural exposures and were made ill from secondary exposure post-application to offices and other establishments. Twenty-five of the 44 occupational cases occurred on farms or landscaping operations.

Both of the high severity cases were occupational. The first high severity case occurred in North Carolina in 2013 and involved a Pest Control Operator making an application when his equipment malfunctioned. The hose was clogged and it burst, exposing the PCO when the contents got on the PCO's skin and his shoes were soaked with the product. The PCO was wearing all label-required PPE during the application. This individual case experienced hyperventilation and was treated in the emergency room for pulmonary edema. The other high severity case occurred in Michigan in 2000 and was a case who had worked spraying pesticides on a farm and presented with shortness of breath and pulmonary edema.

The primary symptom reported by cases was pain and burning or irritation of the eye (n=42). Other commonly reported symptoms include: headache, skin redness and irritation, nausea, and vomiting.

c. National Pesticide Information Center (NPIC) (2011-2016)

The National Pesticide Information Center or NPIC is a cooperative effort between Oregon State University and EPA which is funded by EPA to serve as a source of objective, science-based pesticide information and respond to inquiries from the public and to incidents. NPIC functions nationally during weekday business hours through a toll-free telephone number in addition to the internet (www.npic.orst.edu) and email. Similar to Poison Control Centers, NPIC's primary purpose is not to collect incident data, but rather to provide information to inquirers on a wide range of pesticide topics, and direct callers for pesticide incident investigation and emergency treatment. Nevertheless NPIC does collect information about incidents (approximately 4000 incidents per year) from inquirers and records that information in a database. NPIC is a source of national incident information but generally receives fewer reports than IDS. Regardless, if a high frequency is observed in IDS, NPIC provides an additional source of information to assist in determining whether there is evidence of consistency across national data sets or possibly duplication and additional information about the same incident(s).

From 2010 to December 31, 2015, 111 human incident involving imidacloprid were reported to NPIC. NPIC estimates a certainty index that classifies an incident (including reported symptoms) as definite, consistent (formerly probably or possibly), or inconsistent (formerly

unlikely) with expected exposure to a pesticide, or whether the incident was unclassifiable. Of the 111 reported incidents, 40 were classified as “consistent, possible or probable”⁴ and were further reviewed for symptoms and exposure scenario. Of the 111 reported incidents, 43 incidents were classified as unlikely related to imidacloprid or inconsistent with imidacloprid exposure and 28 incidents were asymptomatic and considered unclassifiable. These incidents were not further reviewed.

Of the 40 reviewed incidents, 24 incidents were classified as minor severity and 16 incidents were classified as moderate severity. Of these 40 incidents, many (n=20) of these incidents occurred following application by a pest control operator (PCO). Individuals reported having contact with a treated surfaces or being exposed to fumes. Nine individuals reported incidents occurring during application, usually because of contact with the product during application. Additional exposure scenarios are described in Table 3.

Table 3. Exposure Scenario Frequency of Imidacloprid Incidents Reported to NPIC (2010-2015)	
Exposure Scenario	Number of Incidents
Residential Exposure Following Application by PCO	20
Residential Exposed During Product Application	9
Exposure to Pet Product	4
Individual Accidentally Sprayed by PCO	2
Accidentally Put Product In Eyes	1
Contact During Product Clean-up	1
Child Ingestion of Treated Soil	1
Residential Drift	1
PCO Exposure During Application	1
Total	40

The symptoms most often reported to NPIC were dermal (n=17), neurological (n=15), respiratory (n=8), gastrointestinal (n=7), ocular (n=5), and cardiovascular (n=1). Note that a patient could exhibit multiple symptoms. Dermal symptoms reported included itching, irritation, rash, hives, redness, swelling, and burning. Neurological symptoms reported include

⁴ Consistent, Probable or Possible means that the majority of reported symptoms are consistent with exposure to the active ingredient according to published information, and the time course between exposure, onset, and duration of symptoms could be conceivably consistent with the toxicology of the active ingredient and the reported exposure pathway is conceivably plausible based on the history provided.

nervousness, confusion, agitation, lightheadedness, seizure, weakness, dizziness, slurred speech, disorientation, and headaches. Respiratory symptoms reported included throat irritation, lung irritation, burning sensation in nostrils, coughing, and difficulty breathing. Gastrointestinal symptoms reported were diarrhea, nausea, stomach pain, and vomiting. Ocular symptoms reported were burning, eye irritation, and redness. Cardiovascular symptoms reported include chest tightness.

d. California Pesticide Illness Surveillance Program (PISP) (2010-2013)

The California Pesticide Illness Surveillance Program (PISP) maintains a database of pesticide-related illnesses and injuries. Case reports are received from physicians and via workers' compensation records. The local County Agricultural Commissioner investigates circumstances of exposure. Medical records and investigative findings are then evaluated by DPR technical experts and entered into an illness registry.

PISP contains both residential and occupational pesticide incidents. PISP has limited coverage (only California) and limited utility for identifying trends over time. However, the incident information is entered by professionals with expertise in pesticides who extensively follow-up on each reported case, establishing a high degree of confidence in the information provided for each reported incident. PISP, however, does not conduct severity coding for cases.

Ninety-six cases were reported to PISP between 2010 and 2013 that involve the active ingredient imidacloprid in combination with other pesticides. Only three of these cases involved the single ingredient imidacloprid. All of the reported cases were classified as having either a definite (n=1), a probable (n=53), or a possible (n=42) relationship with imidacloprid. Seventy five cases were occupational and 21 cases were non-occupational. Incidents were most often reported to occur to field workers usually as the result of drift or postapplication.

There were 33 reported cases of drift exposure. Five of these exposures occurred in non-agricultural settings as a result of an agricultural application. The other 28 cases, stemmed from two events, and were exposures to field workers as a result of an agricultural application in a nearby field. The exposure scenarios are presented in Table 4.

Table 4. Exposure Scenario Frequency of Imidacloprid Incidents Reported to PISP (2010-2013)	
Exposure Scenario	Number of Incidents
Occupational (N=75)	
Field Worker	70
Applicators	5
Non-Occupational (N=21)	
Drift (as a result of Agricultural Application)	5
Postapplication Exposure	5
Direct Contact with Product	3
Ingestion (1 intentional, 2 unintentional)	3
Accidentally Put Product in Eyes	2
Exposure During Application of Product	3
Total	96

The health effects reported include: neurological, respiratory, gastrointestinal, ocular, musculoskeletal, dermal and cardiovascular (Table 5).

Table 5. CA PISP Health Effects Reported from Imidacloprid Exposure			
Effect	Occupational	Non-Occupational and Unknown	Total
Neurological	44	9	53
Gastrointestinal	39	5	44
Respiratory	42	7	49
Ocular	25	4	29
Dermal	11	2	13
Musculoskeletal	12	2	14
Cardiovascular	4	0	4

Note that a patient could exhibit multiple symptoms. Neurological symptoms reported include shaking, confusion, headache, lightheadedness, anxiety, dizziness, tingling skin, and drooling. Gastrointestinal symptoms reported include vomiting, nausea, dry heaves, diarrhea, abdominal pain, and upset stomach. Respiratory symptoms reported included sinus, coughing, difficulty breathing, congestion, itchy/sore throat, dry throat, tightness/discomfort in chest, and

shortness of breath. Ocular symptoms reported were blurred vision, watering eyes, burning eyes, itchy eyes, and red eyes. Dermal symptoms reported include rash, peeling skin, blisters, redness, itching, and skin irritation. Musculoskeletal symptoms reported include generalized body aches, extreme fatigue, and muscle pain. Cardiovascular symptoms reported include Bradycardia, tachycardia, palpitations, and high blood pressure.

e. Agricultural Health Study (AHS)

The AHS is a federally-funded study that evaluates associations between pesticide exposures and cancer and other health outcomes and represents a collaborative effort between the US National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), CDC's National Institute of Occupational Safety and Health (NIOSH), and the US EPA. The AHS participant cohort includes more than 89,000 licensed commercial and private pesticide applicators and their spouses from Iowa and North Carolina. Enrollment occurred from 1993 – 1997, and data collection is ongoing. The AHS maintains a list of publications resulting from AHS studies⁵. If there are AHS findings in the published literature relevant to a pesticide undergoing registration review, the Agency will ensure these findings are considered in the problem formulation/scoping phase of the registration review process and, if appropriate, fully reviewed in the risk assessment phase of the process. Imidacloprid is not included in the AHS, and therefore this study does not provide information for this report.

IV. CONCLUSION

A review of incident in IDS, NPIC, SENSOR-Pesticides and California PISP by HED found that the acute health effects reported for imidacloprid are consistent among the databases queried. These health effects primarily include dermal, neurological, respiratory, and gastrointestinal effects. HED did not identify any aberrant effects outside of those anticipated. These effects are generally mild/minor to moderate and resolve rapidly.

In both IDS and SENSOR-Pesticides, the most commonly reported exposure scenario was exposure to pet products either during application or post application. These pet product-related incidents are primarily residential cases.

In NPIC, the most commonly reported incidents were post application exposure to imidacloprid following application by a PCO. In California PISP, drift and post application exposures were reported the most often for residential exposure to imidacloprid.

The IDS incident trend for imidacloprid, from 2006 to 2016, was reviewed. The imidacloprid incidents reported to IDS from 2006 to 2016, appear to be increasing from 2006 to 2015, then decreasing in 2016. The number of Seresto Collar (Reg. No. 11556-155) incidents reported to IDS was reviewed. The number of incidents reported to IDS have increased every year from 2013 to 2016. Due to the fact that Seresto Collar is a relatively new product that was registered on March 16, 2012, the Agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

⁵ Agricultural Health Study: Publications <https://aghealth.nih.gov/news/publications.html>

Although there are a relatively large number of imidacloprid incidents reported to IDS and SENSOR-Pesticides, the majority of these incidents were classified as minor severity. Minor severity means that a person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved rapidly and usually involved skin, eye or respiratory irritation. Further, a majority of the imidacloprid incidents reported to Main IDS and to SENSOR-Pesticides involved exposure to multiple active ingredients. Incidents involving multiple pesticides are considered to provide less certain information about the potential effects of exposure from a particular pesticide.

Appendix A.

Imidacloprid Incidents Reported to Main IDS from January 1, 2015 to April 26, 2016

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
027771 - 00005	2/28/2015	EADS, TN	011556-00155	SERESTO SMALL DOG	MAJOR	A 68 year old female was secondarily exposed to Seresto Small Dog collar to her hand while petting her dog. Immediately, she experienced taste disorder. Later she felt joint pain.
027872 - 00028	6/29/2015	REEDLEY, CA	072155-00029	COMPLETE INSECT KILLER FOR SOIL AND TURF CONCENTRATE	MODERATE	A 51 year old male used the product through a hose sprayer; 6 months prior he began seeing 1/8' long white worms coming out of his skin and he can feel them moving inside of him. He can especially feel them at night when he moves his body and he will occasionally involuntarily "tense up." He sees tracks underneath his skin where the worms have been as well as bruises. He continued using the product 3 months before calling and ultimately found that there was a "white, elastic, stretchy substance" that was clogging his hose and was moving upon inspection.
027861 - 00008	4/26/2015	ATLANTA, GA	011556-00155	SERESTO SMALL DOG	MODERATE	A 56 year old female with no known medical conditions was exposed to 3 Seresto small dog collars after petting her dogs that had collars placed around their necks. One day later the woman had blepharitis, dry skin around her eyes, epiphora, and ocular irritation.
028036 - 00003	7/5/2015	FAIRFAX, CA	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 6 year old boy was exposed to an unknown amount of K9 Advantix II Extra Large Dog after the product was applied to the family dog. The next day he developed an erythemic rash and urticaria on his hands and arms.
028767 - 00011	3/30/2016	RANCHO CORDOVA, CA	011556-00152	ADVANTAGE II LARGE CAT	MODERATE	A 35 year old male in good condition but concomitant medical history of hypersensitivity to caffeine was administering Advantage II Large Cat and some of the product contacted his thumb. Within ten minutes, he became dizzy and felt a tingling in his throat.
027440 - 00001	1/1/2015	LEWES, DE	011556-00155	SERESTO LARGE DOG	MODERATE	A 61 year old male in fair condition and history of seasonal allergies and hypertension applied Seresto Large Dog collar to his pet who remains asymptomatic. The man also ate a caramel corn stick that he had never eaten previously just prior to applying the collar to the pet. Within 1 hour of applying the collar, the man became nauseated, his stomach hurt, and he began vomiting. He also developed hives, pruritus, erythema, and inflammation on his lower trunk near the buttock and genital area.
027440 - 00004	1/9/2015	MA	011556-00155	SERESTO LARGE DOG	MODERATE	Female of unknown age was exposed to Seresto Large Dog and Seresto cat collars that were placed around the neck of animals in the home. Approximately 30 minutes post exposure, the woman had a headache (migraine) and was lightheaded.
027597 - 00001	2/11/2015	FL		K9 ADVANTIX	MODERATE	An adult female fair condition with a dairy allergy, was exposed to an unknown amount of K9 Advantix after applying doses to each of her

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						dogs. On the next day she developed Urticaria that progressively worsened.
027597 - 00002	3/3/2015	QUAKERTOWN, PA	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 64 year old female in fair condition, with concomitant hypertension, arthritis, obesity, and high cholesterol, was administering K9 Advantix II Extra Large Dog to her dog when some of the product contacted one of her hands. The next day she became anorexic and developed pyrexia.
027597 - 00003	3/20/2015	OREGON CITY, OR		ADVANTAGE II	MODERATE	An 11 year old boy, in good condition, with no known concurrent medical condition, was exposed to an unknown amount of Advantage II when he bathed with a dog that had the product applied on an unknown date. After 1 hour, the child exhibited red irritated, itchy skin on his face and facial swelling. The child was diagnosed with an allergic reaction after being taken to an emergency room.
027597 - 00004	3/28/2015	WESTFIELD, NJ	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	An 11 year old boy with no known concomitant medical conditions, rubbed his face in the area where the product had just been applied on his dog. Approximately 8 hours post exposure, the child complained of a burning and tingling sensation on his face. He later developed a rash.
027597 - 00005	3/29/2015	PORTLAND, OR	011556-00155	SERESTO SMALL DOG	MODERATE	A 63 year old woman, in good condition, with no concomitant medical conditions, was exposed to 1 Seresto Small Dog collar when she applied it to her dog. Within four hours, she began to hallucinate, became nauseated, and had a bad taste in her mouth. The hallucinations lasted approximately 4-5 hours and resolved.
027597 - 00006	3/31/2015	NEW CASTLE, PA		SERESTO (UNSPECIFIED)	MODERATE	A 69 year old man, in good condition with no known concomitant medical conditions, was accidentally exposed to 1 Seresto collar while opening the tin. Approximately 5 minutes post-exposure, the man had a burning sensation on his lips, hives on his face, and his eyes were itchy.
027666 - 00001	4/1/2015	TX	011556-00125	ADVANTAGE II MEDIUM DOGS	MODERATE	A 47 year old woman, in poor condition, with ovarian cancer and an unknown venous problem was exposed to an unknown amount of Advantage II Medium Dog while applying it to her dog and some of the product came into contact with her hand. Approximately one hour following the exposure, she developed throat irritation, swollen lymph glands, difficulty breathing, and difficulty swallowing.
027666 - 00002	4/9/2015	WARRIORS MARK, PA	011556-00155	SERESTO LARGE DOG	MODERATE	A 78 year old woman in poor condition with concomitant allergies, asthma, and diabetes was exposed to a Seresto Large Dog collar when she placed it around the neck of her dog. Within one hour, the woman had coughing, wheezing, and throat irritation.
027666 - 00003	4/2/2015	TRADE, TN	011556-00155	SERESTO SMALL DOG	MODERATE	An adult female was exposed to one Seresto Small Dog collar when she placed it around the neck of her dog. Within one day, the woman developed blistering and cracked skin (skin ulceration) on her hand.
027666 - 00004	4/10/2015	SANTA BARBARA, CA	011556-00141	K9 ADVANTIX II	MODERATE	A 56 year old female in fair condition, with a concomitant asthma condition, got an unknown amount of K9 Advantix on her fingers while treating her dog. Approximately 5 days post-exposure, a sign of an

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						urticarial rash appeared on the abdomen, chest, and back that was ongoing.
027666 - 00006	3/15/2015	COVENTRY, RI	011556-00155	SERESTO LARGE DOG	MODERATE	A 40 year old woman in unknown condition with sensitive skin was exposed to an unknown amount of 1 Seresto Large Dog collar when she placed the collar around the dog's neck. Within 4 hours, she developed Urticaria on her forearms.
027666 - 00008	4/23/2015	HOLYOKE, MA	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	An 8 year old male in good condition with sensitive skin was secondarily exposed to an unknown amount of K9 Advantix II Large Dog when he pet the dog that had the product applied. Approximately 8 hours later, the individual felt a tingling sensation on his cheek.
027666 - 00009	4/21/2015	FLUSHING, MI	011556-00155	SERESTO LARGE DOG	MODERATE	An adult female was secondarily exposed to the Seresto Large Dog collar that was applied to the dog in the home. Within one day, she developed Urticaria on her chest and abdomen.
027666 - 00011	4/25/2015	SPRINGDALE , AR	011556-00130	ADVANTAGE II EXTRA LARGE DOG	MODERATE	A 53 year old female was exposed to Advantage II Extra Large Dog. Within 1 minute, she experienced tachycardia, muscle tremor, and hot flushes.
027704 - 00001	3/22/2015	SAN JUAN, CA	072155-00110	BAYER ADVANCED HOME PEST BED BUG AND FLEA KILLER CONTINUOUS SPRAY	MODERATE	Caller (64 year old female) sprayed her sheets with the product and slept on them for two nights. She reports developing red, pruritic bumps on her torso with a few on her arms immediately after she slept on the sprayed sheets.
027704 - 00002	4/22/2015	GALENA, OH	000432-01483	TEMPRID SC INSECTICIDE	MODERATE	Adult female of unknown age who was exposed when she tried to clean up "drip marks" of the product with her bare hands. Later that night she had a swollen red face, hands that were red and irritated, and her throat was closing -- causing difficulty breathing.
027771 - 00001	4/12/2015	SIXES, OR	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 70 year old male in unknown condition, with no known concomitant medical conditions, accidentally got an unknown amount of the product on his finger and then later put his finger in his eye. Immediately after exposure, the finger became numb. Within one week, the man became disoriented, ataxic, and developed mydriasis.
027771 - 00002	5/3/2015	LOS ANGELES, CA	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 50 year old female in good condition with no known concomitant medical condition was exposed to an unknown amount of K9 Advantix II Extra Large Dog when accidentally got some of the product onto her hands while treating her dogs. She touched her cheek and developed skin irritation and tingling.
027771 - 00003	4/21/2015	WEST CAMP, NY	011556-00155	SERESTO LARGE DOG	MODERATE	A 6 year old boy with no known concomitant medical conditions, lives in the same home of the pet of which the collar was applied. Within 24 hours of application, the human developed an erythemic rash, and dry skin on his lower face and neck. The collar was removed from the dog and the human applied moisturizer on the affected area.

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027771 - 00004	5/3/2015	MEDFIELD, MA	011556-00155	SERESTO LARGE DOG	MODERATE	A 47 year old woman in fair condition with concomitant medical condition of Grave's disease, applied 1 Seresto Large Dog collar to her dog. The dog rubbed against the owner's legs during a walk. Within 6 hours, the human developed a rash on the back of her legs and hives on her legs, abdomen, chest, face, and arms. The woman also had tightness in her throat and chest, and swelling in her lip and tongue. She was pruritic, and had a temperature of 100. She was diagnosed with an allergic reaction when she went to the Emergency Clinic.
027771 - 00006	4/1/2015	HAMPTON, NH	011556-00155	SERESTO SMALL DOG	MODERATE	An adult female with a concomitant medical condition of chronic obstructive pulmonary disease, was secondarily exposed to 1 Seresto Small Dog collar that was placed around the neck of a dog. On an unspecified date post application to the dog, her concomitant condition worsened and she had increased breathing difficulty.
027771 - 00007	4/28/2015	COLUMBUS, GA	011556-00155	SERESTO SMALL DOG	MODERATE	A 48 year old man in good condition, with allergies, was exposed to a Seresto Small Dog collar when he pet a dog that was wearing the collar. Within 1 hour, the individual developed pruritus, hives, and a rash on his arms, back, and abdomen. The individual took an oatmeal bath and an unknown medication.
027771 - 00008	2/16/2015	RICHMOND, VA	011556-00155	SERESTO DOG (UNSPECIFIED)	MAJOR	A 48 year old woman in good condition with an allergy to sodium tetraborate was exposed daily to an unspecified amount of Seresto Dog collars after touching multiple dogs that had the product applied. The woman had erythema, pruritus, Urticaria, blepharitis, and lip edema.
027771 - 00009	5/4/2015	GROVE CITY, PA	011556-00155	SERESTO LARGE DOG	MODERATE	A 45 year old woman in unknown condition, with allergies, was exposed to an unknown amount of active ingredients from 1 Seresto Large Dog collar after applying it to the dog in the home and making contact with the dog daily. Within a week, the woman had developed a rash on her arm.
027771 - 00010	5/4/2015	GROVE CITY, PA	011556-00155	SERESTO LARGE DOG	MODERATE	A 9 year old boy in good condition, with concomitant seasonal allergies, was in contact with a canine in the home who had 1 Seresto Large Dog collar placed around the neck. Within a week, the boy had a rash on both legs.
027771 - 00011	5/16/2015	SPRINGVILLE, AL	011556-00152	ADVANTAGE II LARGE CAT	MODERATE	A 54 year old female administered 1 tube of Advantage II Large Cat to her feline. After applying the product she immediately washed her hands. There was no indication that she had any contact with the product during or after applying it to the cat. The product had been applied to the cat previously without any issue. Three hours after the product was applied to the cat, she developed Urticaria on the dorsal aspect of the neck and wrist, pharyngeal edema, and pruritus. The next day she developed dyspnea.
027771 - 00012	5/19/2015	NORTHFORD, CT	011556-00155	SERESTO LARGE DOG	MODERATE	A 24 year old woman in good condition with no concomitant medical conditions was exposed to an unknown amount of 1 Seresto Large Dog

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						collar when she was playing with the dog after application. Approximately 15 minutes post exposure, the individual had Urticaria on her arms, neck, and face.
027771 - 00013	5/23/2015	SPRINGFIELD, MA	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 20 year old woman with no known concomitant medical conditions, was exposed to an unknown amount of K9 Advantix II Large Dog while she slept with the dog who had the product applied. Approximately eight hours post exposure, the woman had a headache and a bad taste in her mouth. Her tongue and lips were numb.
027771 - 00014	5/24/2015	HIGHTSTOWN, NJ	011556-00155	SERESTO SMALL DOG	MODERATE	A 47 year old woman in fair condition who had ulcerative colitis and no thyroid gland took an unknown dose of cetirizine. Approximately 4 hours later, the woman was exposed to an unknown amount of 1 Seresto Small Dog collar when she was holding a dog who was wearing the collar. Approximately 15 minutes post exposure the woman had Urticaria on her neck and chest.
027771 - 00015	4/8/2015	IN	011556-00155	SERESTO (UNSPECIFIED)	MODERATE	A 58 year old male with allergies, was exposed to dogs and cats wearing Seresto collars on a daily basis. Within a week, the man exhibited pruritus and erythema on his hands, feet, and legs.
027771 - 00016	4/15/2015	IN	011556-00155	SERESTO (UNSPECIFIED)	MODERATE	A 56 year old female was exposed to dogs and cats wearing Seresto collars on a daily basis. Approximately two weeks later the woman began exhibiting erythema and pruritus on her hands, feet, and legs.
027812 - 00001	4/27/2015	SAN ANTONIO, TX	000499-00540, 001021-01767, 001021-02569	BTB ALPINE FLEA INSECTICIDE, BEDLAM BED BUG SPRAY, BEDLAM PLUS	MODERATE	A 55 year old woman who works in a building where the product was utilized. Within 30 minutes or less of entering the building, she experienced voice loss, nasal irritation, respiratory depression, and fatigue. She was also diagnosed with pneumonia.
027704 - 00006	4/24/2015	MILLER, SD	000264-00997	RAXIL MD EXTRA W SEED TREATMENT	MODERATE	A 42 year old man who was exposed through a drift and developed redness on his face. He was exposed to the product again two weeks later, at which point he inhaled some of it while in the treatment area. For three weeks, he had aching muscles, diarrhea, and vomit.
027788 - 00005	4/28/2015	WA	072155-00073	3-IN-1 INSECT, DISEASE & MITE CONTROL READY-TO-SPRAY	MODERATE	Caller is the exposed patient's wife. The husband (63 year old man) sprayed the product around the home and did not wash up afterwards. Several hours later while out hiking with his friends, he experienced a "mild seizure" where his left leg went numb and he experienced convulsions but did not lose consciousness. Apparently a similar episode happened 2-3 weeks before this incident and he had also just recently applied the product.
027788 - 00007	4/19/2015	SAYREVILLE, NJ	072155-00029	BAYER ADVANCED COMPLETE INSECT KILLER FOR SOIL AND TURF CONCENTRATE	MODERATE	A 46 year old woman used the product while wearing PPE. A few days later, she developed redness and peeling skin on her hands, wrists, and neck, and bleeding cracks on her hands. She also experienced a migraine. When she went to the MD, she was diagnosed with chemical burns.

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027872 - 00025	6/18/2015	FORT PIERCE, FL	072155-00073	3-IN-1 INSECT DISEASE & MITE CONTROL CONC	MODERATE	A 44 year old man who sprayed a bush with the product and one of the leaves flipped some of the diluted product back into his eye. Caller states he went inside and flushed it out for approximately 5 minutes but his eye was still slightly red.
027872 - 00026	6/14/2015	DRESDEN, ME	072155-00094	DISEASE CONTROL FOR ROSES, FLOWER & SHRUBS	MODERATE	A 63 year old man stated that he used the product on some plants in his garden. He said that it rained and he watered the roses afterwards. He states that he then was touching the roses (four days after applying the product on them) and was scratched by the thorns. Within half of a day's time, he developed dizziness, confusion, exhaustion, and a headache.
027872 - 00030	6/11/2015	GRETNA, LA	000432-01331-073748, 000264-00598	I MAXXPRO 2F (MASTERLINE), TERMIDOR(R) SC INSECTICIDE	MODERATE	Caller (63 year old male) states that the product was applied by a PCO and while it was being applied, a malfunction of equipment occurred, which caused the hose to flood product fluid -- approximately 10-15 gallons throughout his home. Caller states that since the PCO left after the incident, he was forced to clean up the product by himself and did not wear PPE. The first set of symptoms began two hours after the incident. Overall, symptoms included hypertension, anorexia, nausea, vomiting, polyuria, urinary incontinence, dehydration, acute kidney disease, elevated sodium levels, irritability/agitated, confusion, headache, muscle weakness, feeling faint, slurred speech, miosis, mydriasis, respiratory irritation, laryngitis/voice loss.
027872 - 00031	6/22/2015	FORT MYERS, FL	000432-01455	MAXFORCE FLY SPOT BAIT	MODERATE	A 32 year old female describes that her manager sprays the product daily around her workplace. She and her coworkers are exposed for about 8-11 hours each day as the product is on the walls, handrails, and floor. She feels that her symptoms which include coughing phlegm, HA, and sinus pressure may be caused or exacerbated by the product.
027861 - 00001	5/5/2015	WEST MILFORD, NJ	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	An adult female was exposed secondarily exposed to the product that was applied to her dog. The next day she developed a pruritic erythemic rash on her forearms and legs. She was seen by a dermatologist and prescribed betamethasone cream. A biopsy was performed that showed inflammation and irritation.
027861 - 00002	6/2/2015	WHITNEY POINT, NY	11556PA32	K9 ADVANTIX II	MODERATE	An 11 year old male was exposed to the product while playing with a dog that had been treated with the product. Approximately four hours later, he experienced tingling and numbness on his face.
027861 - 00003	6/2/2015	TOMS RIVER, NJ	011556-00155	SERESTO CAT	MODERATE	A 56 year old female applied a Seresto Cat collar to her cat. The next day she experienced nausea, abdominal cramping, intermittent hot flashes and dizziness.
027861 - 00004	3/26/2015	PORT SAINT LUCIE, FL	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MAJOR	A 45 year old female was exposed to the product after cuddling with her dog that been treated with the product. Seven days later, she developed headache and lethargy. A month later, she was re-exposed to

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						the product when she applied it to her dog. She developed lower back pain/musculoskeletal pain.
027861 - 00005	6/12/2015	RANCHO CORDOVA, CA	011556-00141	K9 ADVANTIX II SMALL DOG	MODERATE	A 63 year old male with a history of diabetes and hypertension, administered a tube of the product to his dog. He touched the wet product with his hands and then touched his nose. The next day his nose became swollen and erythemic. He was seen by a doctor who prescribed antibiotics.
027861 - 00006	6/10/2015	STILWELL, KS	011556-00155	SERESTO LARGE DOG	MODERATE	A 14 year old male was lying next to a dog that was wearing a Seresto collar. Approximately one hour later, he developed urticaria. He took an antihistamine and the symptoms resolved.
027861 - 00007	6/17/2015	PISCATAWAY, NJ	011556-00155	SERESTO LARGE DOG	MODERATE	A 62 year old male with a history of hypertension, was exposed to multiple Seresto Collars when he placed them on his dogs. Immediately post exposure, he had a chemical taste in his mouth. Later that day, he pet his dogs and the chemical taste returned.
027861 - 00009	6/25/2015	OH	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 39 year old male with a concomitant medical condition of respiratory signs due to a cold, treated his dog with the product. Approximately three hours later, he touched the wet application site on his dog. Within a few minutes, he developed hyperhidrosis, pale skin and nausea.
027861 - 00010	6/12/2015	SAN PEDRO, CA	011556-00155	SERESTO LARGE DOG	MODERATE	A 9 year old female with allergies to grass, dust, and dogs was exposed to poison ivy and ticks. About seven days later, she was secondarily exposed to a Seresto Dog Collar that was on the dog of the home. Three days later she developed cellulitis and started on antibiotics and a steroid treatment. She developed hives after completion of her treatment and did another course of antibiotics and a steroids.
027861 - 00012	1/1/2015	RAYNHAM, MA	011556-00155	SERESTO DOG	MODERATE	An adult female, placed a Seresto dog collar on her dog. Approximately, 2 weeks later, she developed erythema and blisters on her hands. Approximately 3 weeks later, she blisters were healing but she developed pustules and nausea.
027861 - 00013	6/15/2015	NISKAYUNA, NY	011556-00155	SERESTO SMALL DOG	MODERATE	A 57 year old male with hypertension, Type II diabetes, and high cholesterol, was exposed to a Seresto Small dog collar that had been placed on the dog of the home. He touched the collar and within 30 minutes he developed blisters, hives and erythematous rash on both hands. He treated the rash and it resolved. He touched the collar again and developed erythematous rash and hives.
027928 - 00001	6/27/2015	NJ		K9 ADVANTIX II (UNSPECIFIED)	MODERATE	A tube of K9 Advantix II was applied to the dog in the home. The dog laid on the chest of a 47 year old female, with seasonal allergies. Approximately 8 hours post exposure, she developed a tingling sensation on her chest. Approximately 3 days later, she developed erythema, irritation and a swollen rash on her chest so she went to a medical professional

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						where she was diagnosed with dermatitis. She was started on an unknown dose regime of steroids and diphenhydramine.
027928 - 00003	7/13/2015	MENDON, NY	011556-00155	SERESTO LARGE DOG	MODERATE	A 64 year old female, with asthma and a mold allergy, was exposed to 2 Seresto Large Dog Collars when she opened the tins. Immediately post exposure, she experienced a burning sensation of her eyes, nose, and hands/application site tingling. She applied the collars to her dogs wearing gloves and thoroughly washed her hands with soap and water after administration. She continued to experience the symptoms when in contact with the product.
027928 - 00004	7/6/2015	COMPTON, CA	011556-00155	SERESTO LARGE DOG	MODERATE	An 82 year old woman, with concomitant drug allergies to penicillin, hypertension, high cholesterol and arthritis, was secondarily exposed to an unknown amount of a Seresto Dog Large Dog collar when she placed the collar around the neck of her dog. Immediately post exposure, she was dizzy.
027928 - 00005	7/6/2015	CHICAGO, IL		K9 ADVANTIX II (UNSPEDIFIED)	MODERATE	A 71 year old man, with a concomitant medical condition of possible allergy to poison ivy, was accidentally exposed to an unknown amount of K9 Advantix II that he applied to his dog. He washed his hands with an unknown soap after application of the product. Four days later, he had hives, rash and pruritus in an unknown location. He was examined by an emergency physician and given 60 milligrams of prednisone. The pruritus stopped but the hives and rash worsened.
027928 - 00006	7/20/2015	CA	011556-00142	K9 ADVANTIX II MEDIUM DOG	MODERATE	An adult female, administered one tube of K9 Advantix II Medium Dog topically to her dog. Approximately 3 and a half hours following the application of product to the dog, she developed a tingling sensation to her chin and near her lip. She washed her skin with hand soap and liquid dish soap. The clinical signs continued.
027928 - 00008	7/15/2015	HOLBROOK, NY	011556-00155	SERESTO LARGE DOG	MODERATE	An adult female was exposed to an unknown volume of Seresto Dog Collars while administering 2 Small Dog collar s and 4 Large Dog collars to her dogs. Immediately post exposure, she had a tingling sensation on the skin of her nose and around her mouth.
027928 - 00009	7/28/2015	KNOXVILLE, TN	011556-00151	ADVANTAGE II SMALL CAT	MODERATE	A 51 year old female administered Advantage II Small Cat to her feline. Since product application she has been petting the cat. Two days post application, she developed hypersalivation, a bad taste in her mouth and a headache.
027928 - 00010	4/25/2015	SPRINGDALE, AR	011556-00130	ADVANTAGE II EXTRA LARGE DOG	MODERATE	A 53 year old female was exposed to an unknown amount of Advantage II Extra Large Dog when it got on her hands while she was applying it to her dog. She immediately washed her hands with soap and water but then experienced tachycardia, trembling and flushed warm sensation. The signs decreased and resolved after approximately 1 hour. No treatments or diagnostics were performed.

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027928 - 00011	4/19/2015	STONE RIDGE, NY	011556-00155	SERESTO LARGE DOG	MODERATE	An adult male was exposed to a dog that had a Seresto Large Dog collar placed around the neck. Two days later, the man exhibited urticaria and red dots (erythema). The man was seen by a doctor and treated with diphenhydramine, hydrocortisone and recommended to shower.
027983 - 00001	8/25/2015	SUMMERFIELD, NC	002724-00351, 000432-00772, 000432-01483	ZOECON GENTROL IGR CONCENTRATE, DELTA DUST INSECTICIDE, TEMPRID SC INSECTICIDE	Death	A resident passed away at a residence that was treated with 3 different chemicals. A pest control company applied Temprid SC mixed with Gentrol to control bed bugs. They also used Delta Dust. Five days later, the resident died. The care giver of the resident thought there was a strong odor and was hospitalized and treated for nausea & vomiting and claims there was chemical exposure. An autopsy was done and they are awaiting results. Caswell County Sheriff's department has an ongoing investigation until they get the coroner report.
027999 - 00005	7/17/2015	VA	001021-02569	BEDLAM PLUS	MODERATE	A 31 year old female is a PCO who applied the product in a large cubicle environment to treat for bedbugs. She experienced difficulty breathing and went to the emergency room and was given respiratory treatment, and an inhaler and released.
028036 - 00001	8/2/2015	SAPULPA, OK	011556-00155	SERESTO SMALL DOG	MODERATE	A 25 year old man, with concomitant acid reflux and hypertension, was exposed to an unknown amount of a Seresto Small Dog collar when he removed the collar from the neck of the dog to bathe him. Approximately 6 hours post exposure, he was nauseated, vomited once, and then felt dehydrated.
028036 - 00002	8/3/2015	OREGON, OH	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 65 year old female was exposed to an unknown volume of K9 Advantix II Large Dog after the product was administered to her dogs and the dogs slept in the same bed as the individual. The next day, she experienced a tingling sensation on her face. The human washed the affected area and the symptom improved.
028036 - 00004	8/4/2015	MACON, GA	011556-00155	SERESTO CAT	MODERATE	A 28 year old woman was exposed to an unknown amount of a Seresto Cat collar when she applied the collar around the neck of the cat. Approximately a week later, her eyes were red and she had swelling in her lips and face.
028036 - 00005	8/5/2015	CARRIERE, MS		ADVANTAGE II (DOG UNSPECIFIED)	MODERATE	A 67 year old female was exposed to an unknown volume of Advantage II after the product was applied to her dog and the dog slept with the individual in her bed. The next day, she had an unknown size swelling on her arm and a headache.
028036 - 00006	6/1/2015	ATHENS, TN	011556-00155	SERESTO LARGE DOG	MODERATE	A 67 year old male, with hypertension, was exposed to a Seresto Large Dog collar that was applied to the dog of the home. He routinely pets and handles the dog. He developed pruritic welts on hands. He used an unknown topical cream on his hands. Two months later, the symptoms had worsened.
028036 - 00007	8/15/2015	PLYMOUTH, MI	011556-00152	ADVANTAGE II LARGE CAT	MODERATE	A 19 year old female, with a concomitant medical condition of hypothyroidism, then pet the feline who had been treated with

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						Advantage II Large Cat and got the product on her hand. She then proceeded to bite her nails. Her lip and tongue became numb, and she became dizzy. The femal brushed her teeth and the numbness of her lip resolved.
028036 - 00009	8/18/2015	CUNNINGHAM, TN		K9 ADVANTIX II (UNSPECIFIED)	MODERATE	A 47 year old female, with concomitant medical condition of allergy and asthma, was exposed to an unknown amount of K9 Advantix II after being in contact with a dog that had the product applied. Within 1 hour she had a tingling and numb sensation on her face.
028036 - 00010	8/8/2015	COVENTRY, CT	011556-00141	K9 ADVANTIX II SMALL DOG	MODERATE	A 55 year old woman was exposed to an unknown amount of K9 Advantix II Small Dog when she applied the product to her dog. Three days later, she bathed the dog with a medicated shampoo and an oatmeal conditioner. Immediately after the bath, she had itchy and watery eyes, facial swelling, erythema on the face, a rash on her skin, an upset stomach, and was lethargic. Approximately a week later, she bathed the dog again and the clinical signs continued. Immediately after the bath, she administered two unspecified eye drops. Two day later, the clinical signs resolved.
028036 - 00011	8/1/2015	DELRAY BEACH, FL	011556-00142	K9 ADVANTIX II MEDIUM DOG	MODERATE	A 67 year old female, in poor condition with asthma and hypertension, was secondarily exposed to an unknown amount of K9 Advantix II Medium Dog via an unknown route after applying the product to her dog. The woman was on unspecified regimens of an unspecified asthma medication and an unspecified hypertension medication since an unknown date in 2013. At an unspecified date later that month, post exposure, the woman had dyspnea.
028036 - 00013	8/26/2015	CINCINNATI, OH	011556-00155	SERESTO SMALL DOG	MODERATE	A 30 year old woman, with Williams syndrome treated with an unknown beta blocker daily, was exposed to a Seresto Small Dog collar that was on her dog. Approximately 90 minutes post exposure, she woke up from a nap with a swollen lip. She was examined by an emergency physician and diagnosed an allergic reaction to the beta blocker.
028036 - 00014	8/19/2015	FRESNO, CA	011556-00155	SERESTO LARGE DOG	MODERATE	A 29 year old woman, with seasonal allergies, was exposed to an unknown amount of 2 Seresto Large Dog collars when she placed the collars around the necks of her dogs. Immediately post exposure, she washed her hands with an unspecified soap. Approximately 1 hour post exposure, she had swelling around the eyes, pruritus, and hives. Two days later, the collars were removed from the dogs. The next day she was examined by an urgent care physician and administered an unspecified injection.
028036 - 00015	8/26/2015	VISTA, CA	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 19 year old female with asthma, was accidentally exposed to an unknown amount of K9 Advantix II Large Dog on her hand, while

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
						applying it topically to the dog. After application she washed her hands with an unknown soap. Approximately 10 minutes post exposure she was dizzy and nauseous.
028066 - 00027	8/17/2015	DOVER, OH	072155-00029	BAYER ADVANCED COMPLETE BRAND INSECT KILLER FOR SOIL AND TURF READY-TO-SPRAY	MODERATE	An 87 year old male applied the product to his yard two weeks ago. Four days after application, he developed a red, itchy rash on his hands. H was seen by a doctor and was prescribed a steroid cream and his symptoms cleared up in less than one week.
027796 - 02960	5/30/2015	MAUMEE, OH	000228-00500-000538	SCOTTS PROFESSIONAL FERTILIZER 22-0-8 WITH GRUBEX PRO	MODERATE	An adult female walked through the lawn after it was treated with the product and now has a rash on her foot.
027858 - 00015	3/9/2015	CA	000432-01547, 000432-01312, 000432-01363	BROMACIL TECHNICAL, MERIT 2F INSECTICIDE, TEMPO SC INSECTICIDE	MODERATE	A mobile home park was treated by a pest control company with Temp SC, Merit 2F and Core Teet pesticides to a mobile home park to control the Asian Citrus Psyllid (ACP) pest. An adult female developed flu like symptoms; itchy eyes, congestion, runny nose and lethargy. Later that day, she and her husband left the mobile home park and did not return home until CDFA concluded the pesticide applications. That night her husband developed flu like symptoms with a cough and continued to feel ill until he was hospitalized, seven days later. He was released from the hospital the next day. About a week later, he returned to see a physician for the same symptoms. The couple had a history of on-going medical issues that dated back several decades.
028097 - 00001	8/24/2015	MA	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	An adult female administered K9 Advantix II Large Dog to her canine. Approximately 8 hours after applying the product to the dog, she developed urticaria on the arms and other unspecified locations. She was examined by a Dermatologist who determined the urticaria was due to exposure to the product. Prednisone and an unspecified cream were prescribed for treatment.
028097 - 00002	9/11/2015	HUBERT, NC	011556-00155	SERESTO SMALL DOG	MODERATE	A 29 year old man was exposed to an unknown amount of 1 Seresto Small Dog collar when he placed the collar around the neck of the dog. Approximately 15 minutes post exposure, the individual developed pruritus, erythema, and urticaria on his arms and legs. The individual began taking cetirizine and his clinical signs improved.
028097 - 00003	8/26/2015	COTTONWOOD, ID	011556-00155	SERESTO SMALL DOG	MODERATE	A 57 year old female, with concomitant environmental allergies and asthma, was in contact with a dog who had 1 Seresto Small Dog collar placed around the neck. Approximately 2 days later, she became dizzy, developed malaise and was dyspneic. The collar was removed from the dog on approximately and the symptoms improved.

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
028097 - 00004	1/1/2015	PA		ADVANTAGE II (CAT - UNSPECIFIED)	MODERATE	An 86 year old woman, who had a concomitant erythematous rash, was exposed to an unknown amount of Advantage II after it was applied to her cat. An unspecified amount of time post exposure, the erythema rash worsened. About one month later, she was examined by a dermatologist, administered an unspecified injection, and started on an unknown cream and tablets.
028097 - 00005	6/10/2015	VALENCIA, PA	011556-00155	SERESTO LARGE DOG	MAJOR	An adult female was exposed to a Seresto Large Dog collar after placing the collar around her dog's neck. On an unspecified time after the collar placement on the dog, she developed respiratory irritation. Three months later, the collar was removed from the dog and disposed of and the respiratory sign resolved.
028097 - 00006	1/1/2015	JULIAN, PA	011556-00155	SERESTO (UNSPECIFIED)	MAJOR	An adult male was exposed to 1 Seresto Dog Collar after it was applied to the dog. An unknown time post exposure, the human was nauseated. 3 months post onset of symptom, the collar was removed from the dog and the adult male recovered.
028097 - 00007	8/29/2015	BALDWIN, NY	011556-00155	SERESTO LARGE DOG	MODERATE	A 60 year old female applied one Seresto Large Dog collar to her dog. She continued to have daily normal exposure to the collar. Nine days later, she exhibited nausea, lethargy, and dizziness.
028097 - 00009	7/1/2015	OMAHA, NE	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 54 year old man, with allergies, was exposed to an unknown amount of K9 Advantix II Large Dog after making contact with the dogs in the home that had been treated with the product. On an unknown date that same month, he developed pruritus and a rash on his neck, chest, and back. He was examined by a physician and was administered an unknown steroid injection and applied topical diphenhydramine ointment.
028097 - 00010	1/1/2015	INVERNESS, FL	011556-00155	SERESTO SMALL DOG, SERESTO LARGE DOG	MODERATE	An adult female, with inhalant allergies, was exposed to Seresto Small Dog and Seresto large Dog collars that were applied to the dogs of her home. On unspecified dates when she was close to the dogs wearing the collars her nose would become congested. The sign resolved after away from the dogs. Approximately four months later, the collars were from the dogs and placed the collars back in the tins. She would also get congested when she was near the tins. She placed the tins in a cabinet where she is no longer near them and the sign resolved.
028097 - 00012	5/1/2015			ADVANTAGE II (CAT- UNSPECIFIED)	MAJOR	An adult female was exposed to an unknown amount of Advantage II on her hand from contact with the recently treated cat of the home. Approximately 12 hours post exposure, she had an erythematous irritation on her chest. She was seen by her doctor who suspected she had experienced a heart attack. She applied an unknown burn cream and an antibiotic ointment to the affected area and the signs resolved. At another time, she experienced a sting/burning sensation on legs feet chest and back which was worse when she wakes.

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028097 - 00013	6/6/2015	VA	011556-00155	SERESTO LARGE DOG	MAJOR	A 60 year old male was exposed to a Seresto Large Dog after making contact with it in while applying to his dog. Approximately 1 week post exposure, the man had a bad taste in his mouth. Approximately three months later, the collar was removed from the dog in the home and a Seresto Small Dog collar was placed on the dog. His signs resolved.
028097 - 00014	8/14/2015	GULFPORT, MS	011556-00155	SERESTO LARGE DOG	MODERATE	A 36 year old woman was exposed to a Seresto Large Dog collar during application to the dog in the home. Approximately two days later, she had urticaria on her arms. She applied an over-the-counter topical hydrocortisone cream to the affected areas. She recovered without medical intervention.
028097 - 00015	8/26/2015	BROOKLYN, NY	011556-00155	SERESTO LARGE DOG	MODERATE	A 27 year old male was started on an unspecified regimen of allergy injections by a medical doctor. A year later, he placed a Seresto Large Dog collar around his dog's neck. Approximately 30 minutes post collar application to the dog, he developed a rash on his chest. Approximately 7 hours post collar application to the dog, his rash spread to his arms and hands. He took an unspecified dose of diphenhydramine orally. Approximately 18 hours post collar application to the dog, he developed urticaria on his arms and blepharitis of one eye. He was examined by a doctor and treated with unspecified doses of hydroxyzine and prednisone. The urticaria improved.
028118 - 00020	8/3/2015	MOORE, OK	072155-00071	3-IN-1 INSECT DISEASE & MITE READY-TO-USE	MODERATE	A 57 year old female used the product. Some of the product got on her leg. She rinsed her leg with a hose and took a bath that evening. She has been experiencing exhaustion and weakness in her legs.
028201 - 00001	9/28/2015	PA	011556-00155	SERESTO SMALL DOG	MODERATE	An adult female, who had a sensitivity to many chemicals, was exposed to 1 Seresto Large Dog collar and 1 Seresto Cat collar when she placed the collars around the necks of the pets. Two hours post handling the collars, the woman exhibited dry eyes. The next day, she exhibited joint pain, a headache, and nausea. Four days after application, she touched a collar when applying the dog's leash and immediately exhibited tachycardia.
028201 - 00003	10/5/2015	COLDWATER, MI	011556-00155	SERESTO LARGE DOG	MODERATE	A 59 year old woman, in fair condition, with an acoustic brain tumor, was exposed to 1 Seresto Large Dog collar when placing it around the neck of a dog. Approximately 5 minutes post exposure, the woman had tingling in her fingertips, a dry and numb sensation in her mouth and on her lips, a headache, then vomited.
028201 - 00004	9/23/2015	PATCHOAGE, NY	011556-00142	K9 ADVANTIX II MEDIUM DOG	MODERATE	A 70 year old woman, allergies to cats and dogs, high cholesterol, fibromyalgia, spinal stenosis and asthma, was exposed to an unknown volume of K9 Advantix II Medium Dog when the product was applied to her dog and an unknown environmental flea spray was used at an

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
						unknown frequency. The next day, she developed pain on respiratory inspiration. The sign continued with the symptom being worse at night and occasionally during the day.
028201 - 00010	10/13/2015	PA	011556-00141	K9 ADVANTIX II SMALL DOG	MODERATE	An adult female was accidentally exposed to an unknown amount of K9 Advantix II Small Dog while applying to the dog. Approximately 5 minutes post exposure, she felt a tingling sensation on her hand.
028201 - 00011	10/16/2015	SANDY CREEK, NY	011556-00155	SERESTO SMALL DOG	MODERATE	An adult female was exposed to an unknown amount of 1 Seresto Small Dog after applying the collar to her dog. Three days later, she developed erythemic urticaria, a burning sensation localized to her chest and a burning sensation on her lips. She washed her chest. Approximately 2 hours post onset, the erythemic urticaria and a burning sensation localized to her chest resolved.
028201 - 00013	10/22/2015	GREENWOOD, IN	011556-00141	K9 ADVANTIX II SMALL DOG	MODERATE	A 34 year old female, with allergies, was accidentally exposed an unknown amount of K9 Advantix II Small Dog through inhalation. Approximately 1 hour post application, the woman was holding the dog and inhaled the product, and approximately 15 minutes post accidental exposure, the woman had tightness in her jaw, nausea, throat tightness and difficulty swallowing.
028201 - 00014	8/1/2015	ROCHELLE, IL	011556-00155	SERESTO LARGE DOG	MODERATE	A boy of unknown age was exposed to 1 Seresto Large Dog collar when the product was applied to the dog in the house. Approximately 2 hours post exposure, the boy had generalized urticaria. On an unspecified date, the collar was removed and the urticaria resolved without medical intervention.
028289 - 00001	8/1/2015	WARRENTON , MO	011556-00155	SERESTO DOG (UNSPECIFIED)	MODERATE	An 80 year old female, with hypertension and heart palpitations, placed one Seresto Dog collar around the neck of her canine. Approximately two months later, she developed pruritus, welts, and open sores. She was examined by her medical doctor and diagnosed with Sarcoptes mange. Approximately five months post initial exposure, she presented to a dermatologist who started her on a treatment regimen of prednisone, hydroxyzine, and a permethrin topical.
028289 - 00002	9/21/2015	GURNEE, IL	011556-00142	K9 ADVANTIX II MEDIUM DOG	MODERATE	A 65 year old female, with allergies, administered K9 Advantix II Medium Dog to her dog. After application the dog laid on the couch. At an unspecified time the same day the owner sat on the couch in the same location of the dog and immediately felt a tingling sensation on her back.
028289 - 00003	11/11/2015	SAINT FRANCISVILLE, LA	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 4 year old male was exposed to a dog that had K9 Advantix II Extra Large Dog applied topically the previous day. The child was hugging the dog and was bathed after playing with the dog. The next day, the child exhibited a rash on his cheeks and arms. The child was taken to the doctor and treated with an unknown cream.

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028289 - 00004	11/16/2015	VANDERGRIFF, PA	011556-00141, 011556-00142	K9 ADVANTIX II SMALL DOG, K9 ADVANTIX II MEDIUM DOG	MODERATE	A 55 year old, with a concomitant medical condition of seasonal allergies, was secondarily exposed to an unknown amount of K9 Advantix II Medium Dog and K9 Advantix II small dog that was applied to the dogs in the household. Approximately 1 hour post administration of the product to the dogs the man felt dizzy and lethargic.
028289 - 00005	11/13/2015	FARMINGTON, NY		K9 ADVANTIX (UNSPECIFIED)	MODERATE	An adult female, with a concomitant medical condition of seasonal allergies, was secondarily exposed to an unknown amount of K9 Advantix that had been applied to the dog on an unspecified date. Approximately 3 hours post exposure to the pet, the woman had blisters on her forearms. On an unspecified date post exposure, the woman was examined by a physician and administered a tetanus injection and unspecified type of antibiotics. The physician diagnosed second or third degree burns.
028289 - 00006	11/19/2015	OAK HARBOR, WA	011556-00128	ADVANTAGE II SMALL DOG	MODERATE	A 27 year old male applied Advantage II Small Dog to a pet. It is not known if he washed his hands after application, and he then proceeded to eat a burrito. Approximately 1 hour after the product was applied to the pet, he began to experience nausea, vomiting, dry mouth, and became disoriented.
028289 - 00008	11/17/2015	SAINT MARYS, GA	011556-00152	ADVANTAGE II LARGE CAT	MODERATE	A 56 year old woman was secondarily exposed to an unknown amount of Advantage II Large Cat when applied to the cat. Immediately following administration, the individual smelled the product and began to have difficulty breathing and developed irritation in her nose and throat. Approximately 8 hours post exposure, the cat's neck was washed with a cloth. Approximately one week later, the clinical signs continued and she developed a blister in her nose.
028289 - 00009	10/25/2015	CHICAGO, IL	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 39 year old male was secondarily exposed to an unknown amount of K9 Advantix II Large Dog while applying the product to his dog. The next day, he had complete loss of vision in one of his eyes. He developed swelling around the eye and epiphora. He was examined by a physician and optometrist. A month later, he had abnormal vision in the eye.
028289 - 00010	10/1/2015	SACRAMENTO, CA	011556-00155	SERESTO DOG (UNSPECIFIED)	MODERATE	An adult male administered one Seresto Dog collar to his dog. Later that month, he exhibited coughing and a headache.
028289 - 00011	1/1/2015	SAN ANGELO, TX	011556-00155	SERESTO SMALL DOG	MODERATE	An adult female touched a Seresto Small Dog collar that had been placed on a canine. An unspecified time following the exposure, the individual developed tingling in her fingers and arms.
028289 - 00012	9/30/2015	CUMMING, GA	011556-00127	ADVANTAGE II LARGE DOG	MODERATE	An adult female was exposed to an unknown amount of Advantage II Large Dog via an unknown route when she opened the product to apply to her dogs. Immediately upon opening a tube she experienced a

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
						headache and nausea. Approximately 60 hours post product exposure, the symptoms resolved without medical treatment.
028289 - 00013	11/29/2015	SAN ANGELO, TX	011556-00155	SERESTO SMALL DOG	MODERATE	An adult female was exposed to a dog wearing Seresto Small Dog collar. The dog's owner removed the collar so the woman could groom the dog. When the woman was handling the dog she exhibited redness on her arm and a headache. The woman recovered one hour later.
028289 - 00014	11/29/2015	WOODBINE, NJ	011556-00155	SERESTO LARGE DOG	MODERATE	A 59 year old female, with concomitant medical conditions of allergies and mitral valve prolapse, applied 1 Seresto Large Dog collar to her dog. On approximately three months later, the dog and the collar had a malodor and the woman felt nauseated for approximately 20 minutes. The collar was removed from the pet and placed in bags and the individual recovered.
028341 - 00001	11/17/2015		011556-00155	SERESTO SMALL DOG	MODERATE	An adult female was exposed to a dog that had a Seresto Small Dog collar removed prior to contact. The woman did not have direct contact with the Seresto collar. Immediately after handling the dog, the woman developed nausea, and dizziness. She washed her hands and arms with soap and water. The woman fell on the floor (muscle weakness) one minute later as she was walking. She remained dizzy on the floor for 10 minutes. The woman recovered 16 hours post exposure.
028341 - 00002	12/3/2015			K9 ADVANTIX II (UNSPECIFIED)	MODERATE	A 68 year old female, with an allergy to rubber and latex, was exposed to an unknown amount of K9 Advantix II via an unknown route after applying the product to her dog. Approximately 12 hours post product exposure, the woman developed erythema and tingling of her upper lip.
028341 - 00003	12/2/2015		011556-00144	ADVANTAGE II (CAT-UNSPECIFIED), K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 42 year old female, with concomitant conditions of systemic scleroderma, mixed connective tissue disease, and back and neck disorders, was exposed to an unknown amount of K9 Advantix II Extra Large Dog and Advantage II after applying them to her pets. The individual was also taking unknown doses of hydroxychloroquine, lubiprostone, metoclopramide, cimetidine, estradiol, venlafaxine hydrochloride, alprazolam, Vitamin B12, oxycodone, and metaxalone. Docusate, ondansetron, and cyclosporine since unknown dates in 2015. Approximately 8 hours post exposure, the individual felt confused, was ataxic, collapsed, fainted (syncope), and had numbness of her fingers.
028341 - 00005	11/17/2015		011556-00155	SERESTO LARGE DOG	MODERATE	A 52 year old female was exposed to 1 Seresto Large Dog collar when she placed it around her dog's neck. Approximately 8 hours post exposure, the individual developed diarrhea. The next day, the Seresto Collar was removed from the dog. Three days later, the individual's diarrhea resolved.
028341 - 00006	9/1/2015		011556-00155	SERESTO LARGE DOG	MAJOR	A 44 year old female was exposed to 3 Seresto Large Dog collars when she applied them to her dogs, one of which sleeps in her bed.

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						Approximately 4 days post exposure, the human developed eyelid inflammation and a burning sensation of her lips. The signs continued intermittently and she began to apply vitamin E oil to the affected skin. Approximately three month later, the collar was removed from the dog who sleeps in her bed. The signs continued and no medical examination has been sought.
028341 - 00007	7/1/2015		011556-00155	SERESTO SMALL DOG	MAJOR	A 48 year old female, with seasonal pollen allergies, placed 1 Seresto Small Dog collar on her dog. Sometime within the next week, the owner removed the dog's collar to bath it. She put the collar back on the dog and approximately 15 minutes post collar exposure, the she developed a burning feeling to her right thumb. The thumb developed numbness and was hot inside and out and throbbed with each heartbeat.
028341 - 00008	12/23/2015		011556-00141	K9 ADVANTIX II SMALL DOG	MODERATE	A 38 year old man was exposed to an unknown amount of K9 Advantix II Small Dog when applying the product to the dog. He was petting the dog after the application and may have had accidental exposure to the product. Approximately 1 hour post exposure, the individual was dizzy. Approximately 4 hours post exposure, the individual was nauseated, had a headache, and began having diarrhea.
028341 - 00009	12/23/2015			K9 ADVANTIX (UNSPECIFIED)	MODERATE	An adult male was exposed to an unknown amount of K9 Advantix when applying the product to his dog. Approximately 1 hour post exposure, he was nauseated, dizzy, hallucinating, and had a sore throat.
028341 - 00010	12/8/2015			K9 ADVANTIX II (UNSPECIFIED)	MODERATE	A 57 year female had direct contact with two dogs following application of K9 Advantix II. Approximately three days later, the human developed dermal swelling, erythema, and scaly skin on both of her arms. She was seen by a medical physician on three different occasions over the next two weeks. She was placed on an oral antibiotic, prednisone, and 2 unspecified topical creams. The clinical signs continued and the affected area on her arms appeared as a chemical burn and her hands were swollen.
028341 - 00011	12/30/2015		011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 44 year old woman, who had a mild peanut allergy, was exposed to an unknown amount of K9 Advantix II Extra Large Dog when she got product on her left thumb and index finger during application to the dog. Immediately post exposure, the individual washed her hands with dish soap and had a tingling sensation in an unspecified location.
028354 - 00002	10/2/2015	SUWANEE, GA	072155-00029	COMPLETE INSECT KILLER FOR SOIL AND TURF READY TO SPRAY	MODERATE	A 50 year old male sprayed the product onto his yard and got the diluted product on his hands while spraying it and then scratched his forehead in three places. He took a shower when he was done with application. Two to three days later, he developed three pink spots on is forehead.

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028422 - 00001	1/6/2016	WESTFIELD, MA	011556-00141	K9 ADVANTIX II SMALL DOG	MODERATE	A 25 year old woman was secondarily exposed to an unknown amount of K9 Advantix II Small Dog when the dogs, who had the product applied, slept in the same bed as the individual. The next day, she developed a tingling sensation on the right side of her face.
028422 - 00002	1/9/2016	WASHINGTON, IL	011556-00141, 011556-00143	K9 ADVANTIX II SMALL DOG, K9 ADVANTIX II LARGE DOG	MODERATE	A 58 year old female, with concomitant medical conditions of irritable bowel syndrome, angioma and a torn tendon in her shoulder, applied K9 Advantix II Small Dog to one dog and K9 Advantix II Large Dog another dog in the home. 12 hours after the product was applied she developed a tingling sensation on one hand and became lightheaded after petting one of the dogs.
028422 - 00003	1/8/2016	ERIE, PA	011556-00155	SERESTO SMALL DOG	MODERATE	A 48 year old female, with a concomitant paraben allergy, was secondarily exposed to 1 Seresto Small Dog collar that had been placed around the neck of her dog. A week later, she developed had a pruritic, red bumpy rash on her arms, legs, abdomen and back. She was examined by her physician and started on an unspecified dose oral cetirizine.
028422 - 00004	12/1/2015	CUMBERLAND, RI	011556-00155	SERESTO LARGE DOG	MODERATE	A 70 year old male was exposed to 1 Seresto Large Dog collar when he placed it around the neck of his canine. An unspecified time post exposure, he developed a cough. He was seen by his primary care physician and presented to an urgent care facility, diagnosed with bronchitis, and treated with azithromycin, acetaminophen/codeine, and a cough suppressant containing benzenoid. The cough subsided but then recurred once the acetaminophen/codeine was discontinued.
028479 - 00002	1/1/2016	FL	072155-00073	BAYER ADVANCED 3-IN-1 INSECT, DISEASE & MITE READY-TO-USE SPRAY	MODERATE	An 8 year old male got some product on his face while his father was spraying it. He developed hives and itchiness.
028479 - 00003	1/18/2016	COTTONWOOD, CA	000432-01483	TEMPRID SC INSECTICIDE	MODERATE	An adult female's home was treated on three separate days by a PCO with the product for bed bugs. She experienced coughing, choking and wheezing.
028713 - 00001	2/3/2016	BRYAN, TX	011556-00127	ADVANTAGE II LARGE DOG	MODERATE	A 19 year old male with allergies and a mood disorder (abnormal behavior), was accidentally exposed to an unknown amount of Advantage II Large Dog (Imidacloprid-Pyriproxyfen) topically to his hand while petting the dog. The dog had just had the product applied 20 minutes prior. Approximately 20 minutes post exposure, the man had a headache. The man drank an unknown amount of water. The man was not examined by a physician and the clinical sign continued.
028713 - 00002	2/8/2016	WYNANTSKILL, NM	011556-00142	K9 ADVANTIX II MEDIUM DOG	MODERATE	A 63 year old, female human, in good condition, with no known concomitant medical conditions, was exposed to an unknown amount of

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
						K9 Advantix II Medium Dog (Imidacloprid-Permethrin-Pyriproxyfen) after contact with her recently treated dogs. Approximately 20 minutes post application to the dog the individual had numbness of the skin on the left side of her face.
028713 - 00003	2/16/2016	SWEET VALLEY, PA	011556-00143	K9 ADVANTIX II LARGE DOG	MODERATE	A 31 year old female with no known concurrent medical conditions administered one tube of K9 Advantix II Large Dog to her dog. The next day she exhibited small pruritic red bumps on her arms and stomach. She treated the signs diphenhydramine and hydrocortisone.
028713 - 00004	2/23/2016	LA PLACE, LA	011556-00144	K9 ADVANTIX II EXTRA LARGE DOG	MODERATE	A 57 year old female, in fair condition, with diabetes insipidus and asthma, was exposed to an unknown amount of K9 Advantix II Extra Large Dog when she got it on her hands while applying it to her dog. The woman touched her face 1 hour post exposure and then felt numbness over her entire face.
028713 - 00005	2/24/2016	MS	011556-00118, 011556-00116	DEFENSECARE LARGE CAT FLEA PROTECTION, DEFENSECARE SMALL CAT FLEA PROTECTION	MODERATE	A 54 year old female exposed to an unknown amount of DefenseCare Small Cat Flea Protection and Defense Care Large Cat Flea protection when she applied the products her cats. The next day, the woman exhibited urticaria, edema, and erythema on her neck and chest. She has a history of with allergies 2 herniated discs, and fibromyalgia, and is concurrently taking anti depression medication.
028713 - 00006	2/25/2016	NEW PORT RICHEY, FL	011556-00130	ADVANTAGE II EXTRA LARGE DOG	MODERATE	An adult female, in good condition, with known concurrent medical conditions of allergies, was exposed to an unknown amount of Advantage II Extra Large Dog when the product got on her hands when opening the package. The inside package was crushed and all of the tubes were leaking. She immediately exhibited urticaria and pruritus at the exposure site. She took a shower and then took an unknown amount of diphenhydramine orally. The clinical signs resolved in 1 hour.
028713 - 00007	2/11/2016	CASTLETON ON HUDSON, NY	011556-00155	SERESTO LARGE DOG	MODERATE	A 74 year old male was exposed to 1 Seresto Large Dog collar after the collar was placed on his dog. The dog slept in bed with the man each night. Seven days later, he developed nasal discharge and a cough. He was examined by a doctor and referred to an ear, nose and throat specialist. He was examined by the ear, nose and throat specialist who started him on a regimen of fluticasone propionate nasal spray and saline nasal wash.
028713 - 00008	12/1/2015	SHERRILL, NY	011556-00155	SERESTO LARGE DOG	MODERATE	A 44 year old female, with a concomitant medical condition of sensitive skin, was secondarily exposed to 1 Seresto Large Dog collar that was applied to her dog's neck. About one month later, the woman exhibited a pruritic rash on her hands at the exposure site that waxed and waned. Three months later, she removed the collar from her dog and immediately exhibited a pruritic rash on her fingers and arms, at the exposure site.

Incident Package Report	Incident Date	Location	Registration Number	Product Name	Exposure Severity	Incident Description
028713 - 00009	12/1/2015	SHERRILL, NY	011556-00155	SERESTO LARGE DOG	MAJOR	A 45 year old male was exposed to 1 Seresto Large Dog collar that was applied to a dog. Approximately 2 hours post exposure, he developed a pruritic erythemic rash on his arms and sides where he came in contact with the collar. Approximately one day after not being in contact with the collar, the sign resolved, but returned once the man was in contact with the dog and collar again.
028713 - 00010	2/26/2016	ESCONDIDO, CA	011556-00151	ADVANTAGE II SMALL CAT	MODERATE	A 58 year old female, with hypertension, high cholesterol, and back pain, pet cat who had been treated with the product. Approximately 1 minute post exposure, she developed exposure site tingling which then spread throughout her entire body. She also developed diarrhea. Approximately 2 hours post exposure, the human began having muscle spasms. The muscle spasms lasted approximately 2 hours and resolved without medical intervention.
028713 - 00011	2/29/2016	FL		K9 ADVANTIX II (UNSPECIFIED)	MODERATE	An adult female was exposed to an unknown amount of K9 Advantix II (unspecified) when she kissed the dog where the product had recently been applied. Immediately post exposure, the individual washed her mouth with an unspecified soap and water. The individual then developed tingling on her tongue.
028728 - 00004	2/15/2016	NORTH CHARLESTON, SC	001021-02569	BEDLAM PLUS	MODERATE	A 62 year old male had his home treated by a pest control company for bed bugs. The company used a few different products and came to the home a total of 3 times. He was home at the time of treatment but was not in the room being treated. He developed constipation. He previously had tremors that worsened after the exposure.
028728 - 00006	2/16/2016	DUNMORE, PA	001021-01674-011556, 001021-02597-011556	ADVANTAGE HOUSEHOLD FOGGER, ADVANTAGE HOUSEHOLD SPOT & CREVICE SPOT SPRAY	MODERATE	A 51 year old female used multiple Advantage Household Foggers and has used the Advantage Household Spot and Crevice Spot Spray 3x over approximately 2 weeks to treat an existing flea infestation. She states that the home is still infested with fleas and she is being bit. She has an allergy to flea bites and had a histamine reaction and developed hives all over her chest. She took Benadryl to treat the reaction.
028767 - 00001	11/20/2015	LENEXA, KS	011556-00155	SERESTO LARGE DOG	MODERATE	A 45 year old male with an unspecified cardiac disorder, was exposed to 1 Seresto Large Dog collar when the collar was applied to his dog. Immediately post product exposure, the man developed heart palpitations. The collar was immediately removed from the dog and the symptom resolved without medical treatment.
028767 - 00002	2/28/2016	ZANESVILLE, OH	011556-00155	SERESTO SMALL DOG	MODERATE	A 67 year old female, in poor condition, with concomitant type 2 Diabetes, hypertension, high cholesterol, Obsessive Compulsive Disorder panic attacks, progressive polyneuropathy, allergies to pain medication and many other medications, and seasonal allergies, was exposed to a Seresto Small Dog after it was placed around the neck of her dog . On an unspecified date the woman had a change in her

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						diabetes medications. She developed allergic edema, urticaria, dermatitis and eczema, pruritus. In the hospital she received steroids. She was recovered on follow-up two week later.
028767 - 00003	3/4/2016	BASSETT, VA	011556-00151	ADVANTAGE II SMALL CAT	MODERATE	A 25 year old female, consumed an unknown quantity of distilled alcohol and then was exposed to an unknown amount of Advantage II Small Cat (Imidacloprid-Pyriproxyfen) on her hand after applying the product to a cat in the home and then she was exposed on her lips after she kissed the cat near the application site. She washed her mouth and her hand with an unknown soap. Approximately 1 minute post exposure, she experienced a tingling sensation on her lips. Approximately 4 hours post exposure, she experienced abdominal pain, emesis, chills (hypothermia), sweating and weakness.
028767 - 00004	3/12/2016	HYNDMAN, PA	011556-00155	SERESTO LARGE DOG	MODERATE	A 52 year old female, with seasonal allergies and fibromyalgia, opened the Seresto Large dog collar tin and began reading the package insert. The collar was not removed from the plastic liner. Approximately ten minutes following the opening of the tin, the individual developed a burning sensation, hyper salivating and dizziness. The individual drank water and the clinical signs continued.
028767 - 00006	3/14/2016	VERSAILLES, KY	011556-00155	SERESTO LARGE DOG	MODERATE	A 67 year old male with a sensitivity to smells, asthma, and diabetes mellitus, was exposed to an unknown amount of 1 Seresto Large Dog that was applied to the dog of the home. Approximately 4 hours post application when the dog was sleeping in the bed with the owner, the man had an asthma attack with wheezing and difficulty breathing. The man performed an unspecified nebulization treatment on himself, then recovered from the signs. The next day, when sleeping with the dog in the bed, the man had an asthma attack with wheezing and difficulty breathing. The man performed another unspecified nebulization treatment on himself, then recovered from the signs. Four days later, the collar was removed from the dog and the individual remained asymptomatic.
028767 - 00007	3/16/2016	LITCHFIELD, CT	011556-00155	SERESTO LARGE DOG	MODERATE	A 31 year old male with a concomitant animal allergy, penicillin allergy, and arthritis, was exposed to an unknown amount of 1 Seresto Large Dog collar when he applied it to the neck of the dog. The next day, he developed a rash at the exposure site, hives and was having intermittent breathing difficulty at night. The collar was removed from the dog, but the clinical signs continued.
028767 - 00008	3/21/2016	MOUNT WASHINGTON, KY	011556-00155	SERESTO CAT	MODERATE	A 41 year old female, with preexisting immune and autoimmune disorders, asthma, and allergies, was exposed to 1 Seresto Cat collar when sleeping with the dog at night. Immediately post exposure, the individual had hives on her face and chest. She took an oral

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						antihistamine, washed the affected area and washed her sheets. She was not evaluated by a physician.
028767 - 00009	3/24/2016	JERSEY SHORE, PA	011556-00142	K9 ADVANTIX II MEDIUM DOG	MODERATE	A 56 year old female, with concomitant mold, mildew, grass, and environmental allergies, was exposed to an unknown amount of K9 Advantix II Medium Dog (Imidacloprid-Permethrin-Pyriproxyfen) when she got product on her hands during application to the dog. Immediately post exposure, the individual got product on her lips, which then began to feel tingly and irritated. The individual was not examined by a physician and the clinical signs continued.
028767 - 00010	3/28/2016	WINSTON, OR	011556-00155	SERESTO SMALL DOG	MODERATE	A 58 year old female, with concomitant oak, bee, and seasonal allergies, hypothyroidism, and a history of breast cancer, was exposed to 1 Seresto Small Dog collar when placing it around the neck of the dog. Approximately 8 hours post placement of the collar on the dog, the individual developed a headache, nausea, and vomited once. The next day she removed the collar from the dog, then took an unspecified dose of an unspecified analgesic and omeprazole. She was not evaluated by a physician and the clinical signs continued.